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David T. Read Acting Director Health Assessment Policy Staff, CDER Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852

FEB 19 2003

Dear Mr. Read:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,776,456. The application was filed on April 17, 2002, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)872-9411 (facsimile).

Kam Ferrit Karin Ferriter

Senior Legal Advisor

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for Patent Examination Policy

cc:

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RE: ZEVALIN® (CD20 Monoclonal antibody) Docket No. 02E-0343